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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,720	03/20/2001	Mark W. Mellencamp	041303-0138	2610

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EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	8

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/812,720	Applicant(s) MELLENCAMP, MARK W.
	Examiner Shanon Foley	Art Unit 1648

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22,27,28 and 32-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1,3-6,8,10,12,13,15-22,27,28,33-35,37,39 and 41-43* is/are allowed.

6)☒ Claim(s) *2, 7, 9, 11, 14, 32, 36, 38 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 and 5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

In paper no. 7, applicant cancelled claims 23-26, 29-31 and added new claims 32-43. Claims 1-22, 27, 28 and 32-43 are under consideration.

Election/Restrictions

Applicant's election without traverse of group I in Paper No. 7 is acknowledged.

Information Disclosure Statement

The information disclosure statement filed 8/27/02 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each reference listed that is not in the English language. Applicant has submitted two references by Mayr et al. that are in German. These references have been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 14 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to inactivating agents comprising "derivatives of ethylenimine". The metes and bounds for what would be considered "derivatives" of ethylenimine cannot be determined. This rejection could be obviated by deleting "derivatives of ethylenimine and mixtures thereof'. Suggested language for dependent claims can recite something similar to:

"wherein the ethylenimine of claim X is binary ethylenimine", in order to obtain patent protection for specific derivatives used with the vaccine.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9, 11, 36, 38, and 40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that equine influenza virus (EIV) subtype A1 virus strain A/EQ1/Newmarket/77 and EIV A2 virus strains Newmarket/2/93 and Kentucky/95 are required to practice the claimed invention because they are a necessary limitation for the success of the invention as stated in the claims. Although applicant states where the strains were obtained on pages 11-12, these strains do not appear to be well known in the art and there is no indication in the disclosure that these strains are publicly available. As a required claim element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of ATCC 55804. See 37 CFR 1.802. One cannot practice the claimed invention without the specific strains recited in the claims. One also cannot determine whether a virus has the necessary characteristics without access to the parent virus strains. Therefore, access to the instant EIV strains are required to practice the invention. The specification does not provide a

repeatable method for readily identifying EIV viruses without access to the parent strains and the viruses do not appear to be readily available material.

Deposit of EIV subtype A1 virus strain A/EQ1/Newmarket/77 and EIV A2 virus strains Newmarket/2/93 and Kentucky/95 in a recognized deposit facility would satisfy the enablement requirements of 35 U.S.C. 112., because the strains would be readily available to the public to practice the invention claimed, see 37 CFR 1.801- 37 CFR 1.809.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Allowable Subject Matter

Claims 1, 3-6, 8, 10, 12, 13, 15-22, 27, 28, 33-35, 37, 39 and 41-43 are drawn to allowable subject matter. The prior art does not teach or suggest a vaccine comprising an inactivated EHV-1 KyA virus that protects against EHV-1 and EHV-4.

The closest prior art is as follows:

Macek et al. (US 5,853,715 and EP 0 978 286) teach a monovalent vaccine comprising EHV-1 strain AB69 that protects horses against EHV-1 and EHV-4 associated diseases. The virus is inactivated with binary ethylenimine and administered with a cross-linked acrylic acid polymer. See claims 1-3, 6, 7 and 12 of the US patent. However, neither reference teaches or suggests administering an inactivated KyA virus that protects against EHV-1 and EHV-4 associated diseases. The instant disclosure demonstrates protective efficacy against both viruses with the inactivated EHV-1 KyA strain. These results are not taught or suggested by the prior art.

Matsumura et al. (Veterinary Microbiology. 1996; 48: 353-365) teach detecting serum neutralizing antibodies against EHV-1 and EHV-4 after administration of attenuated EHV-1 KyA and discusses the possibility of the KyA strain being an effective live virus vaccine. However, the reference does not teach or suggest inactivating the strain.

Ellis et al. (JAVMA. 1995; 206 (6): 823-832) compare the efficacy between a monovalent modified-live EHV-1 vaccine and a bivalent EHV vaccine comprising inactivated EHV-1 and EHV-4. However, Ellis et al. do not teach or suggest administering a monovalent inactivated EHV-1 strain or the specific EHV-1 KyA strain claimed.

Zhang et al. (Virology. 2000; 468: 482-492) induces long-term protective immunity in mice with heat-killed EHV-1 KyA. However, the reference does not teach or suggest chemical inactivation or co-administering a cross-linked olefinically unsaturated carboxylic acid polymer adjuvant. The reference also does not suggest any protective efficacy against EHV-4 associated diseases.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley
February 4, 2003

JAMES HOUSEL 2/10/03
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600